

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 1

Reviewed on 12/19/2012

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** **Harmony 2**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Manufacture of dental prothesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

- General MSDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazards identification

- **Classification of the substance or mixture**
Ox. Sol. 2 H272 May intensify fire; oxidizer.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Oxidizing
Contact with combustible material may cause fire.

- Dangerous for the environment**
Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Information concerning particular hazards for human and environment:**
Avoid breathing of grinding dust and vapours. Melted material may cause burns.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonized System (GHS).

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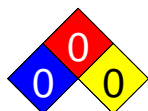
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· **Hazard pictograms**

GHS03

· **Signal word** *Danger*· **Hazard statements***May intensify fire; oxidizer.*· **Precautionary statements***Keep away from heat/sparks/open flames/hot surfaces. - No smoking.**Take any precaution to avoid mixing with combustibles.**Wear protective gloves/protective clothing/eye protection/face protection.**Keep/Store away from clothing/combustible materials.**In case of fire: Use for extinction: CO₂, powder or water spray.**Dispose of contents/container in accordance with local/regional/national/international regulations.*· **Additional information:***Alloys do not require a label, providing they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market.*· **Classification system:**· **NFPA ratings (scale 0 - 4)***Health = 0**Fire = 0**Reactivity = 0*· **HMIS-ratings (scale 0 - 4)***Health = 0**Fire = 0**Reactivity = 0*· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** *Not applicable.*· **vPvB:** *Not applicable.*

3 Composition/information on ingredients

· **Chemical characterization:** *Mixtures*· **Description:** *Dental alloy*· **Dangerous components:**

| | | |
|-----------|-----------|----------|
| 7440-22-4 | silver | 25-50% |
| 7440-05-3 | palladium | 25-50% |
| 7440-74-6 | indium | 25-50% |
| | Zink | 2.5-<10% |

4 First aid measures

· **Description of first aid measures**· **General information:** *No special measures required.*

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- **After inhalation:**
Grinding dust: Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** After contact with the molten product, cool rapidly with cold water.
- **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.
- **After swallowing:** Seek medical treatment.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Do not inhale explosion gases or combustion gases.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Extractors are required on all machines used for thermal processing or splinter removal processes.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

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- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

| | |
|-------------------------|---|
| 7440-22-4 silver | |
| PEL | 0.01 mg/m ³ metal and soluble compounds (as Ag) |
| REL | 0.01 mg/m ³ |
| TLV | 0.1 mg/m ³ metal: dust and fume |
| 7440-74-6 indium | |
| REL | 0.1 mg/m ³ and compounds, as In |
| TLV | 0.1 mg/m ³ |

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:** Usual hygienic measures for dental practice.

- **Breathing equipment:** Use respiratory protective device against the effects of fumes/dust/aerosol.

- **Protection of hands:**

Protective gloves should always be worn during mechanical and thermal processing.

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**

Mechanical processing:

Leather gloves

Strong gloves

Thermal processing:

Heat protection gloves

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Solid

Color: Yellow

- **Odor:** Odorless

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range: 882–1140 °C (1620–2084 °F)

Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

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| | |
|---|---|
| · Auto igniting: | Product is not selfigniting. |
| · Danger of explosion: | Product does not present an explosion hazard. |
| · Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| · Vapor pressure: | Not applicable. |
| · Density at 20 °C (68 °F): | 9.8 g/cm ³ (81.781 lbs/gal) |
| · Relative density | Not determined. |
| · Vapour density | Not applicable. |
| · Evaporation rate | Not applicable. |
| · Solubility in / Miscibility with Water: | Insoluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · Solvent content: | |
| Solids content: | 100 % |
| · Other information | No further relevant information available. |

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
- **Carcinogenic categories**

| |
|---|
| · IARC (International Agency for Research on Cancer) |
|---|

| | |
|-----------|----------|
| 7440-47-3 | chromium |
|-----------|----------|

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

| | |
|-----------|--------|
| 7440-22-4 | silver |
| 7440-50-8 | copper |

· **TSCA (Toxic Substances Control Act):**

| | |
|-----------|----------|
| 7440-57-5 | Gold |
| 7440-22-4 | silver |
| 7440-50-8 | copper |
| 7440-06-4 | platinum |
| 7440-74-6 | indium |
| 7439-88-5 | iridium |

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

| | | | |
|-----------|--------|--|---|
| 7440-22-4 | silver | | |
| 7440-50-8 | copper | | D |

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



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· **Signal word Danger**

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· Hazard statements*May intensify fire; oxidizer.***· Precautionary statements***Keep away from heat/sparks/open flames/hot surfaces. - No smoking.**Take any precaution to avoid mixing with combustibles.**Wear protective gloves/protective clothing/eye protection/face protection.**Keep/Store away from clothing/combustible materials.**In case of fire: Use for extinction: CO₂, powder or water spray.**Dispose of contents/container in accordance with local/regional/national/international regulations.***· National regulations:****· Other regulations, limitations and prohibitive regulations***The product is a medical device according to the EC-directive 93/42/EEC.**This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.***· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

USA